

AD\_\_\_\_\_

Award Number: DAMD17-02-1-0173

TITLE: PCBs Alter Dopamine Mediated Function in Aging Workers

PRINCIPAL INVESTIGATOR: Richard F. Seegal, Ph.D.

CONTRACTING ORGANIZATION: Health Research, Incorporated  
Rensselaer, New York 12144

REPORT DATE: January 2004

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 074-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503				
1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE January 2004		3. REPORT TYPE AND DATES COVERED Annual (15 Dec 2002 - 14 Dec 2003)
4. TITLE AND SUBTITLE PCBs Alter Dopamine Mediated Function in Aging Workers			5. FUNDING NUMBERS DAMD17-02-1-0173	
6. AUTHOR(S) Richard F. Seegal, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Health Research, Incorporated Rensselaer, New York 12144  E-Mail: seegal@wadsworth.org			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES Original contains color plates: All DTIC reproductions will be in black and white.				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) The major hypothesis is that prior occupational exposure to polychlorinated biphenyls (PCBs) results in decrements in neuropsychological and neurological performance and reductions in the number of dopamine (DA) terminals in the basal ganglia. In Albany, NY, 248 subjects (62 per year) will undergo neuropsychological and neurological examinations, complete a comprehensive questionnaire, have blood drawn to measure serum PCB concentration and undergo a non-invasive test to determine bone lead concentrations. This latter measure will allow us to control for exposure to lead-a potential confounder. In New Haven, CT, 96 subjects (24 subjects per year, chosen randomly) will be asked to undergo brain imaging at the Institute for Neurodegenerative Disorders to determine if PCBs reduce the number of basal ganglia DA terminals. To date, despite one of the worst winter in recent history, 62 subjects have undergone testing in Albany and 21 subjects have been image in New Haven, CT. Serum PCB concentrations are being analyzed at Mt. Sinai School of Medicine. Secure electronic databases have been created for all data. We anticipate no problem in continuing to recruit and test the number of subjects needed for studies in both Albany and New Haven to reach our annual goals.				
14. SUBJECT TERMS Polychlorinated biphenyls, dopamine, parkinson's disease, neurological function, aging				15. NUMBER OF PAGES 102
				16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

20040421 064

## Table of Contents

Cover.....	1
SF 298.....	2
Table of Contents.....	3
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	11
Reportable Outcomes.....	11
Conclusions.....	11
References.....	
Appendices.....	11

## **INTRODUCTION**

The major hypotheses to be tested in this project are that high-level occupational exposure to polychlorinated biphenyls (PCBs) in former capacitor workers will result in (i) decrements in performance on neuropsychological and neurological tests that reflect the historic PCB body burden of the individual and (ii) decrements that are correlated, perhaps causally, with reductions in the number of dopamine (DA) terminals in the basal ganglia.

Aging former capacitor workers who had previously been employed at capacitor manufacturing facilities located approximately fifty miles north of Albany, NY are now undergoing neuropsychological and neurological examinations, completing a comprehensive questionnaire, having blood drawn to measure serum PCB concentrations, and undergoing a non-invasive test to determine bone lead concentrations in Albany, NY. This latter measure is being collected to reduce the likelihood of confounding the neurological effects of prior PCB exposure with the neurological effects of prior lead since many workers were also exposed to lead. Finally, approximately 40% of the subjects (chosen on a random basis) are now participating in the second portion of the study that uses brain  $\beta$ -CIT SPECT imaging to determine whether prior occupational exposure to PCBs reduced the number of basal ganglia DA terminals. Imaging takes place at the Institute for Neurodegenerative Disorders in New Haven, CT.

## **BODY**

In order to test the above hypotheses we have gathered a team of internationally recognized experts in the epidemiology of environmental and occupational exposure to PCBs, the neurology of movement disorders and Parkinson's Disease, the assessment of toxicant-induced deficits in neuropsychological function, measurement of serum PCB concentrations, non-invasive determination of bone lead concentrations, and brain imaging of central dopamine neurons and their relationship to movement disorders, including Parkinson's Disease.

## **STUDY INVESTIGATORS**

---

### **Albany, NY Based Testing**

**Richard F. Seegal - Wadsworth Center, New York State Dept. of Health (NYSDOH):**

Principal Investigator

**Edward F. Fitzgerald, Lenore J. Gensburg - Center for Environmental Health, NYSDOH**

Tracing, Screening, Residential, Occupational, Dietary and Medical Histories

**Stewart A. Factor, Eric S. Molho - Albany Medical Center: Neurological Assessment**

**Robert J. McCaffrey - University at Albany: Neuropsychological Assessment**

**Richard F. Haase - University at Albany: Biostatistician**

**Mary S. Wolff - Mount Sinai School of Medicine: Blood Drawn for Serum PCB Analysis**

**Andrew S. Todd - Mount Sinai School of Medicine: Bone Lead Determination**

**Patrick Parsons - Wadsworth Center, NYSDOH: Bone Lead Determination**

---

### **New Haven, CT Based Testing**

**Kenneth Marek, John P. Seibyl - Institute for Neurodegenerative Disorders: Brain Imaging**

The following narrative provides descriptions of the progress we have made in the second year of the project—a period in which we have been actively engaged in data collection.

Please refer to the first progress report for a description of the tasks we carried out in the first year that provided the foundation from which we are now able to carry out the procedures necessary to recruit and test subjects. These tasks included obtaining Institutional Review Board approvals from all participating institutions; the installation and calibration of the K-Shell X-Ray Fluorescence system for the non-invasive measurement of bone lead; the assembly and test piloting of a comprehensive interview/questionnaire and the establishment of procedures for the tracing, screening, recruitment and testing of subjects.

### We Have Met Our Goal for Recruiting and Testing Subjects in 2003!

In the past year we successfully recruited and tested sixty-two subjects in Albany, NY. These tests include administering a residential, occupational, dietary and medical history interview; complete neurological and neuropsychological assessments, measurement of bone lead concentrations and the collection of blood for determining serum PCB concentrations.

A majority of the subjects tested during this last year (49 out of 62) were those who had participated in earlier studies conducted by investigators from the Mt. Sinai School of Medicine in the late 1970's and early 1980's. Those individuals are important because we have access to their archived serum from those studies. Comparisons of current and archived serum PCB concentrations will allow us to 'fine-tune' the algorithms needed to estimate historic serum PCB concentrations based on current serum PCB levels for the remaining subjects for whom we do not have archived sera.

There were 310 potential subjects with archived sera. Table I provides a description of the individuals who were traced, screened and recruited. Tracing refers to the procedures carried out to identify and locate individuals who potentially could take part in the study while screening refers to the procedures carried out by staff at the Center for Environmental Health (a part of the New York State Department of Health) to determine if the individuals were medically eligible (see Appendix 1). Once found to be medically eligible the subjects' names were sent to Ms. Gwen Mergian, the Study Coordinator, who called them to more completely describe the test protocols and schedule their visits to Albany. A sample informational packet sent to the subjects once they agree to participate in the Albany-based portion of the study can be found in (Appendix 2).

At the completion of testing in Albany subjects were randomly asked if they wished to participate in the SPECT  $\beta$ -CIT imaging portion of the study carried out by Dr. Marek's group at the Institute for Neurodegenerative Disorders in New Haven, CT. Despite the fact that these procedures required a two day stay in New Haven and the injection of a radio-labeled tracer, approximately 50% of the subjects who participated in the Albany-based phase of the study agreed to travel to New Haven, CT for brain imaging (Table I). A sample informational packet describing the procedures necessary for brain imaging can be found in Appendix 3.

**TABLE I: Potential Subjects with Archived Sera (n=310)***as of 9 Jan '04*

<b>Tracing Results</b>		<b>Entered Tracing: 310</b>	
Dead		97	31.29%
Out of Area		20	6.45%
Too Young		2	0.65%
Could not be Located		0	0.00%
<b>Eligible for Screening</b>		<b>191</b>	<b>61.61%</b>
Still in Tracing		0	

<b>Screening Results</b>		<b>Entered Screening: 191</b>	
Refused		40	20.94%
Medically Ineligible		59	30.89%
<b>Eligible for Recruitment</b>		<b>92</b>	<b>48.17%</b>
Still in Screening		0	

<b>Albany Testing: Recruitment Results</b>		<b>Entered Recruitment: 92</b>	
Participated		50	56.18%
Refused		39	43.82%
Still in Recruitment		3	

<b>New Haven Testing: Recruitment Results</b>		<b>Entered Recruitment: 50</b>	
Participated		24	51.06%
Refused		23	48.94%
Still in Recruitment		3	

Table II provides a breakdown of the individuals who were part of the initial sub-cohort of 310 who were successfully traced and screened and who either agreed or refused to participate in the Albany portion of the study based on their gender and age. Table III provides similar information concerning the participation rate of subjects asked to participate in the New Haven portion of the study. Not unexpectedly, for both portions of the study, age is a key factor in determining whether the subjects agree to participate, with a greater percentage of individuals in their 70's, 80's and 90's declining to participate.

**TABLE II:** Albany, NY Testing, Potential Subjects with Archived Sera, n=92 (3 still in recruitment)*as of 9 Jan '04*

	<b>YES: 50</b>		<b>NO: 39</b>	
<b>GENDER</b>				
Male	36	72.00%	23	58.97%
Female	14	28.00%	16	41.03%

<b>AGE</b>				
50s	14	28.00%	15	38.46%
60s	18	36.00%	8	20.51%
70s	15	30.00%	10	25.64%
80-90s	3	6.00%	6	15.38%

**TABLE III:** New Haven, CT Testing, Potential Subjects with Archived Sera, n=50 (3 still in recruitment)*as of 9 Jan '04*

	<b>YES: 24</b>		<b>NO: 23</b>	
<b>GENDER</b>				
Male	16	66.67%	18	78.26%
Female	8	33.33%	5	21.74%

<b>AGE</b>				
50s	8	33.33%	5	21.74%
60s	9	37.50%	8	34.78%
70s	6	25.00%	8	34.78%
80-90s	1	4.17%	2	8.70%

**We Have Begun Testing Former Capacitor Workers Who Do Not Have Archived Sera**

As of 9 January 2004 300 subjects had been entered into tracing with 37 individuals still undergoing tracing. Although the N for this sub-cohort is still small, it appears that: (i) a larger number of the potential subjects live more than 100 miles from Albany (a criteria for inclusion in the study) than individuals who had participated in the earlier studies and (ii) a slightly higher percentage of the individuals contacted by Ms. Mergian have declined to participate in the study. This trend, if it continues, may reflect the fact that these subjects had not participated in the earlier study conducted by Mt. Sinai School of Medicine. However, given the large number of potential subjects remaining in the cohort, we should have no problem in recruiting the number of subjects needed to meet our goal of testing 248 subjects during the tenure of the award.

Table IV provides a summary of the results we have thus far obtained from those individuals for whom we do not have archived sera (they did not participate in the earlier Mt. Sinai studies). These potential subjects (N=6488) comprise the majority of the former workers employed at the capacitor factories at either Ft. Edward or Hudson Falls, NY for at least three months between 1946 and 1977.

**TABLE IV: Potential Subjects without Archived Sera (n=6488)**

*as of 9 Jan '04*

<b>Tracing Results</b>		<b>Entered Tracing: 300</b>	
Dead		94	35.74%
Out of Area		45	17.11%
Too Young		2	0.76%
Could not be Located		17	6.46%
<b>Eligible for Screening</b>		<b>105</b>	<b>39.92%</b>
Still in Tracing		37	

<b>Screening Results</b>		<b>Entered Screening: 105</b>	
Refused		8	9.64%
Medically Ineligible		21	25.30%
<b>Eligible for Recruitment</b>		<b>54</b>	<b>65.06%</b>
Still in Screening		22	

<b>Albany Testing: Recruitment Results</b>		<b>Entered Recruitment: 54</b>	
Participated		19	47.50%
Refused		21	52.50%
Still in Recruitment		14	

<b>New Haven Testing: Recruitment Results</b>		<b>Entered Recruitment: 19*</b>	
Participated		0	0.00%
Refused		6	100.00%
Still in Recruitment		13	

\* Delays in recruiting due to Holiday Season

Table V provides gender and age based information on those subjects who have either agreed or refused to participate in the Albany based portion of the study as of 9 January 2004.



**TABLE V:** Albany, NY Testing, Potential Subjects  
without Archived Sera, n=54 (13 still in recruitment)

*as of 9 Jan '04*

	YES: 19		NO: 22	
<b>GENDER</b>				
Male	10	52.63%	14	63.64%
Female	9	47.37%	8	36.36%

<b>AGE</b>				
50s	10	52.63%	6	27.27%
60s	1	5.26%	5	22.73%
70s	7	36.84%	9	40.91%
80-90s	1	5.26%	2	9.09%

#### Measurement of Bone Lead Concentrations by K-Shell X-Ray Fluorescence

We have measured bone lead concentrations in all subjects who participated in the Albany-based portion of the study. Because of the relatively small number of subjects that have been tested (they are divided into sub-groups based on their age and gender because these demographic factors influence bone lead concentrations) we have elected not to present the results of these tests at this time.

#### XRF Calibration

Despite the fact that the X-Ray Fluorescence System has been operating for approximately one year, it is still necessary to calibrate the system on a weekly basis. This procedure requires the collection of fourteen spectra from 'phantom' limbs (*i.e.*, plaster of paris casts doped with varying concentration of lead) to develop weekly calibration lines - a process that takes between 8 to 10 hours per week to accomplish. In addition, spectra from the subjects are interspersed with phantom spectra collected on the same day that bone lead measurements are made. This procedure insures that the calibration data are collected both before and after each subject. In addition, the system is recalibrated on a monthly basis, as needed, to compensate for drift in the spectra.

Ms. Susan Heckman was hired on 23 January 2003 to carry out the bone lead measurements and the necessary calibrations described above. Fifty percent of her salary is charged to this grant and she is supervised by Dr. Patrick Parsons, an analytical inorganic chemist who is Director of the New York State Lead Screening Program. Dr. Parsons collaborates with Dr. Andrew Todd of the Mt. Sinai School of Medicine and Drs. Parsons and Todd have trained Ms. Heckman while Dr. Parsons oversees the procedures necessary for the calibration of the X-Ray Fluorescence system.

We have ordered a second X-Ray detector from Canberra Industries for approximately \$14,600 because early this summer the detector failed. Although Dr. Todd temporarily loaned us a second unit, the time required for Canberra Industries to custom build a new detector (a minimum of six weeks) was felt to be prohibitively long and would negatively influence our ability to meet our schedule of testing.

Measurement of Serum PCB Concentrations

Dr. Mary Wolf of the Mt. Sinai School of Medicine is analyzing serum PCB concentrations from 49 individuals using glass capillary gas chromatographic techniques. Data obtained from these analyses will include not only congener specific determination of current serum PCB concentrations obtained when the subjects traveled to Albany, but also, for those individuals for whom we have archived sera, reanalysis using the same analytical procedures described in the grant application. The availability of both current and archived sera PCB levels, determined in the same laboratory using the same analytical techniques, will allow us to more precisely estimate historic serum PCB levels for those individuals for whom we do not have archived sera.

Investigators Meetings

In order to facilitate communication between these individuals who are located at the different institutions in Albany, we have met seven times during the past year (January 7<sup>th</sup>, February 11<sup>th</sup>, April 22<sup>nd</sup>, May 23<sup>rd</sup>, July 8<sup>th</sup>, October 7<sup>th</sup> and December 16<sup>th</sup>). These meetings have proven to be extremely useful and allow us to avoid many of the pitfalls that might otherwise occur in the conduct of this complicated multi-institutional epidemiological study. Topics discussed include: how to best report results to subjects' physicians if abnormal neurological and neuropsychological deficits are seen; issues of confidentiality and database development for reporting results for statistical analyses.

In March of 2002 a meeting was held in Albany that included all investigators from Albany and New Haven as the epidemiology consultants to discuss setup of the study. In June of 2004 a second all-investigator meeting will be held in Albany to discuss progress to date and initial data analysis.

The Future

We will continue to recruit subjects for study in both Albany, New York and New Haven, CT. Despite one of the worst winters in recent history, we were able to reach our goal of testing 62 subjects per year and we are confident that we will be able to test a similar number of subjects in the coming year.

We would like to collect information on thyroid hormone function in the remaining subjects because it has recently come to our attention that T<sub>3</sub>, T<sub>4</sub> and free TSH levels are altered in workers employed at the La Salle Electrical Utilities Company in La Salle, Illinois who were occupationally exposed to similar levels of PCBs (Final Report to the Agency for Toxic Substances Disease Registry [ATSDR], May 2002). We will request a change in the Statement of Work (SOW), additional monies and, if the request is approved, present modified Consent Forms to the appropriate IRBs for the collection of an additional blood sample. We feel that collection of this additional data is important since the present study will allow us to confirm or reject the findings obtained from a similar occupational cohort.

### **KEY RESEARCH ACCOMPLISHMENTS**

As in all epidemiological studies, presentation of interim results prior to the collection of the entire data set and the accompanying statistical analyses to control for potential confounders is at best misleading and at worse may result in conclusions that are fallacious. Hence, the key research accomplishments are those described in the above sections.

### **REPORTABLE OUTCOMES**

An abstract entitled ‘Does Occupational Exposure to Polychlorinated Biphenyls Alter Dopamine-Mediated Neurological Function?’ was prepared for the 2003 International Neurotoxicology Association (INA9) meeting in Dresden, Germany (see Appendix 4).

### **CONCLUSIONS**

We have met our goals of testing subjects in both Albany, NY and New Haven, CT despite one of the worst winters in recent history. Unlike laboratory-based studies, the subjects, many who are elderly and live a considerable distance from Albany, must either travel alone or be transported by the study coordinator, Ms. Gwen Mergian to Albany.

We feel that our success is based on our dedication and the principle that each individual is treated with the utmost respect and consideration. These efforts have been recognized by a subject who writes for a local paper and has provided a unique perspective of her experiences in Albany (see Appendix 5). We also enclose a study update that we provided to all participants. We will provide additional updates in the coming year (see Appendix 6).

### **APPENDICES**

**Appendix 1:** Telephone Screening Script with Screening Criteria.

**Appendix 2:** Subject Information Packet for Albany, NY Based Testing.

**Appendix 3:** Recruitment Packet for New Haven, CT Based Testing.

**Appendix 4:** Abstract from International Neurotoxicology Association (INA9) Meeting in Dresden, Germany, June 2003.

**Appendix 5:** Local Newspaper Article Written by an Albany Study Subject Describing Her Experience.

**Appendix 6:** First Issue of a Study Update for Participants.

## **APPENDIX 1**

Telephone Screening Script with Screening Criteria  
Used to Determine Medical Eligibility

Name of Potential Participant:

ID:

Name of Interviewer:

Date:

### Screening Telephone Script

Hello, my name is \_\_\_\_\_ and I'm calling from the New York State Department of Health. May I please speak with \_\_\_\_\_?

Mr/Ms \_\_\_\_\_, I'm calling regarding a letter and information sheet mailed to you recently about a research study we are conducting on the effects of PCB exposure in the workplace. Did you receive this letter?

As you may recall from the information sent to you, the purpose of the study is to determine if prior exposure to PCBs on the job increases the likelihood of developing neurological problems.

Do you have any questions about the study?

[IF INSTANT REFUSAL TO PARTICIPATE: No problem. Would you mind answering a 5 minute eligibility interview just so we can close your file and because the information will be helpful to us?]

Would you mind answering a few brief questions now to help us determine whether you are eligible for this project? This information will be helpful to us even if you decide not to participate in the project.

[Screening questionnaire]

Those are all my questions for today. If you choose to participate in this study, you will be paid \$150, lunch will be provided on the day of testing and all travel-related expenses will be reimbursed. Would you be interested in helping us with this study?

[IF NO: Okay. Thank you for your time.]

[IF YES: Great. I'll meet with my supervisor to discuss whether you are eligible for the project. If you are eligible, we will contact you soon to set up an appointment. ]

Thank you for your time. If you have any questions, please feel free to call me toll-free at 866-406-2386.

Name of Potential Participant:

ID:

Name of Interviewer:

Date:

### SCREENING QUESTIONNAIRE

1) Did you ever work in any job, other than at GE, that involved exposure to PCBs?

Yes \_\_\_\_ No \_\_\_\_ Don't know \_\_\_\_ No Response \_\_\_\_

If yes, Name and Address of Company

---

---

If yes, when did you start and stop working there?

Year Started \_\_\_\_ Year Ended \_\_\_\_

If yes, what kind of work did you do?

---

2) I need to ask you some questions about your medical history. Your answers will be kept strictly confidential.

*Without identifying the disease or condition by name*, could you please tell me if **you** have ever been diagnosed or treated by a doctor for any of the following conditions or diseases?

Please wait until the end of the list to give me your answer.

- Multiple sclerosis
- Stroke resulting in a hospital admission
- Brain surgery
- Head injury resulting in a concussion diagnosed by a doctor, or a loss of consciousness or confusion
- HIV/AIDS
- (current) Drug Abuse
- Current consumption of 5 or more drinks of alcohol per day
- Hospitalization for depression or other emotional problems in the past one year

Yes \_\_\_\_ No \_\_\_\_ Don't know \_\_\_\_ No Response \_\_\_\_

Name of Potential Participant:

ID:

Name of Interviewer:

Date:

3. Next I will read a list of medical conditions to you. Can you please tell me if currently or in the past 6 months you have been treated with any drugs for the following conditions?

Please wait until the end of the list to give me your answer.

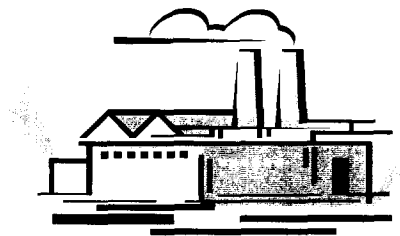
- Psychoses / seeing, hearing or feeling things that are not there
- Epileptic seizures
- Depression / sadness
- Anxiety / nerves
- Shortness of breath

Yes \_\_\_\_

No \_\_\_\_

Don't know \_\_\_\_

No Response \_\_\_\_



# The Capacitor Workers Study

DAMD17-02-1-0173      Annual Report–January 2004  
PCBs Alter Dopamine Mediated Function in Aging Workers  
Seegal, Richard F., Principal Investigator

## **APPENDIX 2**

Subject Information Packet for  
Albany, NY Based Testing



## PERMISSION TO TAKE PART IN A HUMAN RESEARCH STUDY

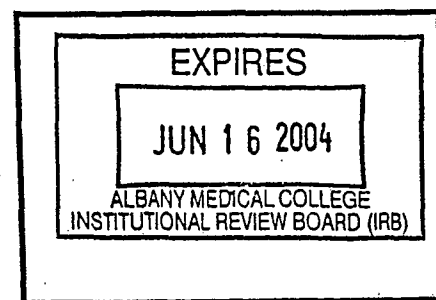
**Title of research study:** Do PCBs Alter Dopamine Mediated Function in Aging Workers?

**Principal Investigators:** Dr. Richard Seegal of the New York State Department of Health and Dr. Stewart Factor and of the Parkinson's Disease and Movement Disorders Center of Albany Medical Center

We invite you to take part in a research study because you may have been previously exposed to polychlorinated biphenyls (PCBs) at your job in either Fort Edward or Hudson Falls, New York. Your name and history of exposure to PCBs at work was obtained from records maintained by the New York State Department of Health from earlier research studies of PCB exposure in workers.

### *What you should know about a research study*

- We give you this consent form so that you can read about the purpose, risks and possible benefits of taking part in this research study. Please review it carefully.
- The main goal of regular medical care is to help each patient. The main goal of a research study is to learn things to help future patients.
- We cannot promise that this research study will help you.
- Just like regular medical care, your taking part in this research study can result in harmful effects that may be minor or serious.
- Someone will explain this research study to you. Feel free to ask all the questions you want before you make a decision.
- A research study is something you volunteer for. Whether or not you take part in this research study is up to you.
- You have the right to choose not to take part in the research study. Also if you agree to take part now, you can change your mind later on.
- Whatever you decide it will involve no penalty or loss of benefits that you would get anyway.



**NOTE:** Do not sign after the stamped date or if the box is not stamped.

JUN 17 2003

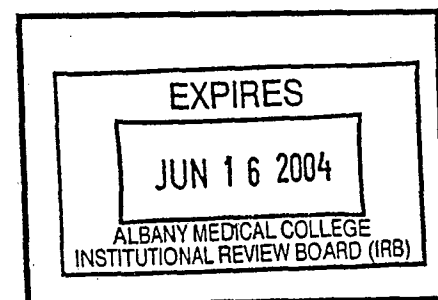
## **1 - Why is this research study being done and what is its purpose?**

The purpose of this research is to determine if a relationship exists between PCB exposure and Parkinson's disease. This research is being done to study if neurological problems exist in people who had been exposed at their job to polychlorinated biphenyls (PCBs), a type of chemical used in factories to make electrical equipment. Understanding the relationships between previous exposure to PCBs at the work site and possible changes in nervous system function may lead to better treatment of workers who have been exposed to high levels of PCBs or other toxic chemicals, including lead which may cause neurological problems similar to those caused by PCBs.

This study will obtain measures of neurological function through physical tests and tests of memory and learning and relate these measures to PCB exposure in people who had been exposed at their job. We expect about 250 people will take part in the study, which will also include estimating lead exposure by measuring bone lead concentrations in your leg (shin) using a test similar to an X-ray. In addition, approximately 35% of the subjects will be chosen to participate in an additional portion of the study conducted at the Institute for Neurodegenerative Disorders in New Haven, CT. Selection will be based on the levels of PCBs in their blood. This portion of the study involves imaging brain function using very low levels of a radioactive compound ( $[^{123}\text{I}]\text{CIT}$ ) and brain scans (Single Photon Emission Computed Tomography—SPECT). Subjects selected for this portion of the study will be given an invitation to participate and a description of the procedures to review prepared by neurologists at the Institute for Neurodegenerative Disorders. Please ask us if you have any questions regarding the purpose of this study.

## **2 - Who is doing the research study?**

Dr. Richard Seegal, a Research Scientist at the New York State Department of Health and Dr. Stewart Factor, a Neurologist at the Parkinson's Disease and Movement Disorders Center of Albany Medical Center are the principal investigators. They, along with Dr. Eric Molho, a Neurologist at the Parkinson's Disease and Movement Disorders Center of Albany Medical Center, Dr. Robert McCaffrey, a Neuropsychologist in the Department of Psychology at the University of Albany, and Dr. Kenneth Marek, a Neurologist at the Institute for Neurodegenerative Disorders in New Haven, CT, are planning to conduct a research investigation. This research is supported by the U.S. Army Medical Research and Materiel Command.



**NOTE: Do not sign after the stamped date or if the box is not stamped.**

JUN 17 2003

### **3 - What can you expect if you take part in this research study?**

You will receive a physical examination that will take approximately 60 minutes. As part of this exam we will measure nerve function, muscle strength and reflexes. You will also be asked to get up from a chair and walk 50 feet in a straight line. You will also be asked to write a sentence and draw with each hand.

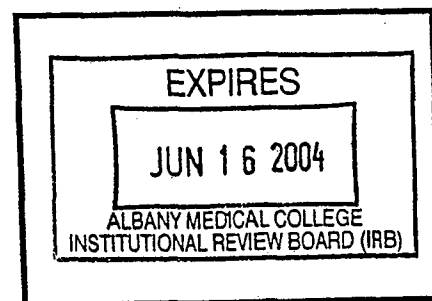
You will also receive tests that measure muscle control, steadiness, and measures of memory and learning. Finally, to learn whether you are feeling depressed or upset, a series of questions will be asked of you. These tests will take approximately 2 to 3 hours to complete.

You will also receive a test called X-Ray Fluorescence which takes a small X-ray of your shin bone to measure the amount of lead in that bone. You will be asked to sit quietly for about 30 minutes while this measurement is made.

We will ask you to complete an interview with a series of questionnaires that will take about one hour to complete. The interviewer will ask questions about where you have lived, where you have worked, your hobbies, your general medical history and your health habits. You have the right to not answer any question and can stop the interview at any time.

You will also be asked to provide a small sample of blood. This sample will be collected from a vein in your arm using a sterile needle, as in a routine blood test. Blood collection will take only a few minutes and will be collected at the Parkinson's Disease and Movement Disorders Center of Albany Medical Center under the supervision of Dr. Stewart Factor. The quantity of blood drawn will be 10cc (two teaspoons). This blood will be taken to measure PCBs and estimate your previous exposure to PCBs. We will also measure DDE, a marker of exposure to pesticides, and lipid levels which are used to report the PCB data. After these measurements have been made, the blood sample will be destroyed. All testing should take approximately 6 to 7 hours to complete.

You will be given the option to complete the testing in one full day in Albany, or to split the testing into two partial days. For instance, the interview could be conducted on the afternoon of the first day at a location either in your community or in Albany. The second day of testing, conducted in Albany, would then take approximately 5 hours to complete. If you prefer, overnight accommodations in an Albany area hotel will be provided.



**NOTE: Do not sign after the stamped date or if the box is not stamped.**

JUN 17 2003

#### **4 - What are the risks and possible discomforts?**

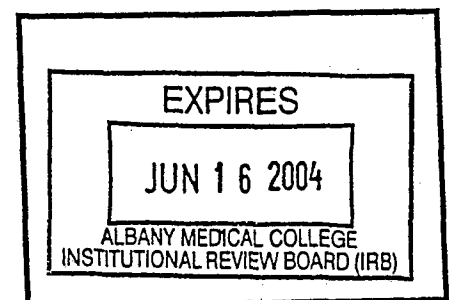
Only a minor risk is involved for all of these procedures. Following the blood collection, some people may experience a small amount of bleeding, swelling, "black and blue mark" or tenderness at the needle entry site. A risk of infection occurs rarely. Discomfort is minimal, resulting only from the initial needle prick. The X-Ray Fluorescence test is painless and involves exposure to only a very small amount of radiation which is approximately one-one thousandth of the exposure from a normal chest X-ray. There are no discomforts associated with the bone lead X-ray measurement and there are no side effects.

#### **5 - What are the possible benefits?**

A possible benefit to participating in this study is that knowledge obtained from the neurological and neuropsychological exams that are part of the research may uncover a previously unknown neurological abnormality. If found, your physician will be notified of this abnormality upon your authorization. Because the measurement of PCBs in blood is not a standard clinical test we can not tell you what these results mean since the relationships between PCB exposure and nervous system function are not presently fully understood. However, results from this study may ultimately aid in understanding the relationships between previous exposure to PCBs at the work site and possible changes in nervous system function.

#### **6 - If you do not want to take part in the research study, are there other choices?**

You are free to choose not to take part in this research study. Taking part in this study is voluntary. If you decide not to take part, there will be no penalty to you. You may also withdraw from the study at any time, without affecting or changing your medical care, by contacting Dr. Seegal toll free at 1-(866) 852-2561.



**NOTE: Do not sign after the stamped date or if the box is not stamped.**

JUN 17 2003

### **7 - If you have any questions or problems, whom can you call?**

If you have any questions about the research study now or later you should call Dr. Seegal toll free at 1-(866) 852-2561. If you think you have been injured by the research, you should call the study doctor, Dr. Factor, or an associate at (518) 452-0914. If you cannot reach them, or if you have any questions about your rights as a research subject, you may call the Albany Medical College, Office for Research at (518) 262-5182. For questions regarding the protection of human subjects call Tony Watson, Administrative Coordinator of the Institutional Review Board of the New York State Department of Health at (518) 474-8539.

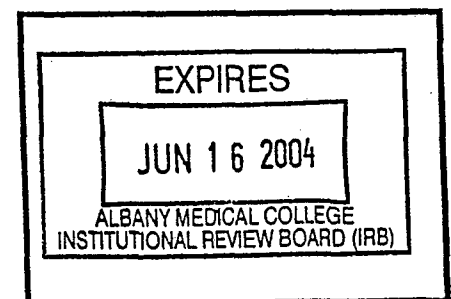
### **8 - What information will be kept private?**

Efforts will be made to keep your personal information, including research and medical records, private. We can not guarantee absolute privacy. Organizations that may inspect and copy your private information include the Food and Drug Administration, the Department of Health and Human Services, the New York State Department of Health and Albany Medical Center. It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

No information will be released to anyone else unless authorized by you. Any information that specifically identifies you will be removed from the blood that is taken. The interview form will not have your name, street address or social security number on it. Results of the study may be published; however, your name will not appear in any report or publication.

### **9 - Can your taking part in the research end early?**

You may decide not to continue in the research study at any time without it being held against you and without losing any benefits you currently have.



**NOTE: Do not sign after the stamped date or if the box is not stamped.**

JUN 17 2003

### ***10 - What else do you need to know?***

You will not be allowed to access your research records.

This study will be carried out at no expense to you.

At the end of your visit to the Parkinson's Disease and Movement Disorders Center of Albany Medical Center you will receive \$150 for your time and will be reimbursed for travel expenses and meals that you may have paid for during your visit.

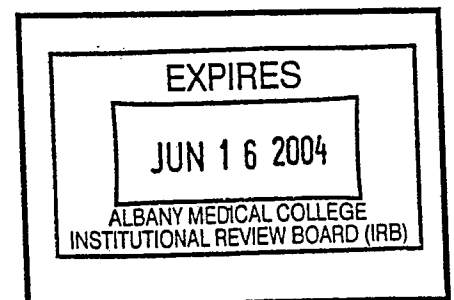
We will give you a signed and dated copy of this consent form.

You will not be informed of individual results, but will be given the results of the research study.

#### **Medical Care for Research Related Injury**

The United States Department of Defense is funding this research project. Should you be injured as a direct result of participating in this research project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator (Dr. Seegal) before you enroll in this study.

Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research.



**NOTE: Do not sign after the stamped date or if the box is not stamped.**

JUN 17 2003

## Do PCBs Alter Dopamine Mediated Function in Aging Workers?

Note: The subject must date the consent form at the time they sign it.

I have read the informed consent form and agree to participate in the research study described.

### CONSENT OF RESEARCH SUBJECT

#### Approval of research subject:

Signature \_\_\_\_\_ Date Signed \_\_\_\_\_

Name (print or type) \_\_\_\_\_

Street \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

#### Consent obtained by:

Signature \_\_\_\_\_ Date Signed \_\_\_\_\_

Name (print or type) \_\_\_\_\_

Title \_\_\_\_\_

#### Witness:

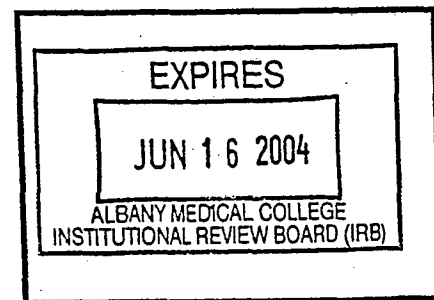
Signature \_\_\_\_\_ Date Signed \_\_\_\_\_

Name (print or type) \_\_\_\_\_

Street \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

(A witness is required when the subject cannot read and the consent document was read to the subject. The sponsor may also require a witness. If a witness is not required, enter "NA" on the signature line.)



**NOTE: Do not sign after the stamped date or if the box is not stamped.**

JUN 17 2003

## Permission to release records to personal physician

I, \_\_\_\_\_, give my permission to have Dr. Stewart Factor/Dr. Eric Molho of the Parkinson's Disease and Movement Disorder Center of Albany Medical Center release medical records (neurological examination) to my personal physician. This will only be done if a previously unknown neurological abnormality is found.

In addition, I give permission to have Dr. Robert McCaffrey of the University of Albany release records (neuropsychological testing) to my personal physician. This will only be done if an abnormality is found.

### PLEASE COMPLETE THE FOLLOWING INFORMATION:

Personal Physician's Name

\_\_\_\_\_

Street Address

\_\_\_\_\_

City, State, ZIP Code

\_\_\_\_\_

Print Participant's Name

\_\_\_\_\_

Participant's Signature

\_\_\_\_\_

Date \_\_\_\_\_

Print Name of Witness

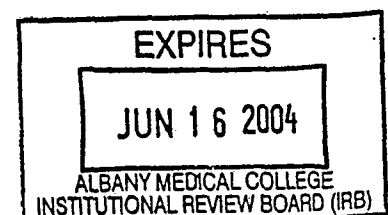
\_\_\_\_\_

Signature of Witness

\_\_\_\_\_

Date \_\_\_\_\_

JUN 17 2003





ID# \_\_\_\_\_

For Office Use Only

## SECTION 1: 25 YEAR RESIDENCE HISTORY

Starting with your *present* residence and working backwards for the past 25 years, please use the tables on the following pages to list *every* residence you have lived at for *one year or more*. For each residence, please indicate the year you first lived there, the year you last lived there, and the address of the residence. Please include second homes if you spent a **total** of 90 or more days per year there, and indicate which month(s) you spent at your second home.

Please also indicate if your residence was in the same building or on the same block (i.e., within an approximate 5 minute walk) as any commercial or industrial establishments, such as: beauty salon, dry cleaners, gas / service station, autobody shops, factories or mills, print shops or photo processing shops, carpentry or furniture repair or refinishing shops. The business must have been there when **you lived** in that house.

**SECTION 1: 25 YEAR RESIDENCE HISTORY (continued)**

			ID# _____ For Office Use Only	
	From Year	To Year	Address	
Residence #1 ..... Current Residence	_____	Current Year _____	Address: _____ _____ City: _____ State: _____ Zip: _____	Is this home in the same building or on the same block (i.e., within a 5 minute walk) as any commercial or industrial establishment?  Yes No
Residence #2 ..... Is / Was This a Second Home? Yes No Months Resided At:	_____	_____	Address: _____ _____ City: _____ State: _____ Zip: _____	When you lived there, was this home in the same building or on the same block (i.e., within a 5 minute walk) as any commercial or industrial establishment?  Yes No
Residence #3 ..... Is / Was This a Second Home? Yes No Months Resided At:	_____	_____	Address: _____ _____ City: _____ State: _____ Zip: _____	When you lived there, was this home in the same building or on the same block (i.e., within a 5 minute walk) as any commercial or industrial establishment?  Yes No

ID# \_\_\_\_\_

For Office Use Only

## **SECTION 2: VOLUNTEER HISTORY**

This section concerns any volunteer work you have done outside the home. Starting with your most *recent* volunteer job and working backwards, please use the tables on the following pages to list the two most recent volunteer jobs that you have held.

For each volunteer job, please refer to the attached sheet titled "Chemical Substances Exposures List" and indicate if you were exposed to any of the chemicals listed on this sheet or any other substances while volunteering.

ID# \_\_\_\_\_

For Office Use Only \_\_\_\_\_

**SECTION 2: VOLUNTEER HISTORY (continued)**

		Dates From To (Mo/Yr) (Mo/Yr)		For each volunteer job, please list any chemicals you were exposed to (refer to the attached list of chemicals).
Most Recent	1)	____/____/____	____/____/____	
		<b>Hours per Week</b> (circle one): <10   11-20 21-30   31-40 40+		
		Company Name _____	City _____ State _____	
		Type of industry: _____	_____	
		Description of work: _____	_____	
		Job Title: _____	_____	
		Company Name _____	City _____ State _____	
		Type of industry: _____	_____	
		Description of work: _____	_____	
		Job Title: _____	_____	
		Company Name _____	City _____ State _____	
		Type of industry: _____	_____	
		Description of work: _____	_____	
		Job Title: _____	_____	

# CHEMICAL SUBSTANCE EXPOSURES LIST

Pesticides or Herbicides

Acids

Lead

Mercury

Halogens (including fluorine, chlorine, bromine, iodine)

Other Metals (including aluminum, tin, copper, nickel, zinc, cadmium, iron)

Sodium, Potassium, Manganese

Minerals (including antimony, beryllium, magnesium, calcium)

Non-metals (arsenic, sulfur, silicon)

Solvents (including perchloroethylene, paint thinner, degreasers, benzene, toluene, isopropanol)

Mirex

HCB (Hexachlorobenzene)

PCBs (Polychlorinated Biphenyls)

DDT (Dichlorodiphenyltrichloroethane)

Radioisotopes

Petroleum Products (gasoline, kerosene, motor oil)

Heavy Cigarette Smoke (second-hand)

Cleaners and Disinfectants (chlorine bleach, ammonia, unspecified, etc.)

Toners and chemicals for photo copier, laser printer, ditto machine

Explosives, fire arms, gun powder and residues

Construction dust, rock or mineral dust, mineral or glass fibers, including asbestos, chalkdust

Refrigerants, freons, coolants

Welding fumes, molten metal fumes

Plastic making fumes

Paper making chemicals

Fire retardant chemicals

Formaldehyde or other aldehydes

Sodium hydroxide, lye, other bases

Carbon Monoxide

Organic dusts (e.g., cotton dust)

Pigments, dyes

Latex paints

Oil-based paints

X-rays

Photographic/negative developing chemicals

Glues and adhesives

Fertilizers

Generic (unspecified) chemicals

ID# \_\_\_\_\_

For Office Use Only

### **SECTION 3: LIFETIME OCCUPATIONAL HISTORY**

This section concerns any paid work you have done outside the home. Starting with your most *recent* paid job(s) and working backwards, please use the tables on the following pages to list *every* job you have held for *one year or more*.

Please also indicate any jobs that you have had **at GE** for *three months or more*.

For each job, please refer to the attached sheet titled "Chemical Substances Exposures List" and indicate if you were exposed to any of the chemicals listed on this sheet or any other substances while *on the job*.

## SECTION 3: LIFETIME OCCUPATIONAL HISTORY (continued)

Are you retired? ☐ No ☐ Yes If yes, in what year did you retire? \_\_\_\_\_

Are you retired? <input type="checkbox"/> No <input type="checkbox"/> Yes		If yes, in what year did you retire? _____		For each job, please list any chemicals you were exposed to (refer to the attached list of chemicals).	
Most Recent	Dates From (Mo/Yr) To (Mo/Yr)		Company Name	City	State
	Hours per Week (circle one): <10 11-20 21-30 31-40 40+				
1)			Type of industry: _____	_____	
			Description of work: _____	_____	
			Job Title: _____	_____	
2)			Type of industry: _____	_____	
			Description of work: _____	_____	
			Job Title: _____	_____	
3)			Type of industry: _____	_____	
			Description of work: _____	_____	
			Job Title: _____	_____	

# CHEMICAL SUBSTANCE EXPOSURES LIST

Pesticides or Herbicides

Acids

Lead

Mercury

Halogens (including fluorine, chlorine, bromine, iodine)

Other Metals (including aluminum, tin, copper, nickel, zinc, cadmium, iron)

Sodium, Potassium, Manganese

Minerals (including antimony, beryllium, magnesium, calcium)

Non-metals (arsenic, sulfur, silicon)

Solvents (including perchloroethylene, paint thinner, degreasers, benzene, toluene, isopropanol)

Mirex

HCB (Hexachlorobenzene)

PCBs (Polychlorinated Biphenyls)

DDT (Dichlorodiphenyltrichloroethane)

Radioisotopes

Petroleum Products (gasoline, kerosene, motor oil)

Heavy Cigarette Smoke (second-hand)

Cleaners and Disinfectants (chlorine bleach, ammonia, unspecified, etc.)

Toners and chemicals for photo copier, laser printer, ditto machine

Explosives, fire arms, gun powder and residues

Construction dust, rock or mineral dust, mineral or glass fibers, including asbestos, chalkdust

Refrigerants, freons, coolants

Welding fumes, molten metal fumes

Plastic making fumes

Paper making chemicals

Fire retardant chemicals

Formaldehyde or other aldehydes

Sodium hydroxide, lye, other bases

Carbon Monoxide

Organic dusts (e.g., cotton dust)

Pigments, dyes

Latex paints

Oil-based paints

X-rays

Photographic/negative developing chemicals

Glues and adhesives

Fertilizers

Generic (unspecified) chemicals



ID# \_\_\_\_\_

For Office Use Only

**SECTION 4: SPORT-CAUGHT FISH CONSUMPTION**

From the following list of freshwater fish, please circle any *sport caught* fish (i.e., fish **not** from a restaurant, fish store or supermarket) caught by yourself **or** someone else that you have consumed in the past **25 years**.

In the space next to each fish you circled, please also note where the fish was caught.

Largemouth Bass	Black Crappie	Salmon Includes Chinook, Atlantic, and Coho Salmon
Smallmouth Bass	White Crappie	Rainbow Smelt
Red eye Bass	Gold Fish	Splake
Striped Bass	Tiger Muskellunge	White Sucker
Rock Bass	Muskellunge	Trout Includes Rainbow, Brook, or Brown Trout (NOT LAKE TROUT)
Bluegill	Yellow Perch	Lake Trout
Brown Bullhead	White Perch	Walleye
Carp	Northern Pike	
Channel Catfish	Chain Pickerel	
White Catfish	Pumpkinseed	

ID# \_\_\_\_\_

For Office Use Only

## **SECTION 5: GENERAL MEDICAL HISTORY**

The tables on the following pages list several medical conditions. Please indicate whether or not you have *ever* been told *by a doctor* that you have had any of these conditions.

If you have ever had any of these conditions, please specify the date you were diagnosed with the condition.

ID# \_\_\_\_\_

For Office Use Only

**SECTION 5: GENERAL MEDICAL HISTORY (continued)****Have you ever been told by a doctor that you had any of the following conditions?**

(Please circle the appropriate response and, if applicable, indicate the date of diagnosis.)

Heart disease	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Heart attack	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
High blood pressure	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Emphysema	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Asthma	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Hay Fever	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Auto-immune disorder (such as Lupus)	Yes	No	I Don't Know	If yes, Specify Type(s) _____ Date(s) of Diagnosis _____
Diabetes	Yes	No	I Don't Know	If yes, Date of Diagnosis _____ Do you take insulin injections? No Yes
Thyroid Disorders	Yes	No	I Don't Know	If yes, What Type _____ Date of Diagnosis _____
Arthritis	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Carpal Tunnel Syndrome	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Other Muscle or Joint Condition	Yes	No	I Don't Know	If yes, What Type(s) _____ Date(s) of Diagnosis _____

ID# \_\_\_\_\_

For Office Use Only

**SECTION 5: GENERAL MEDICAL HISTORY (continued)****Have you ever been told by a doctor that you had any of the following conditions?**

(Please circle the appropriate response and, if applicable, indicate the date of diagnosis.)

Gastrointestinal Ulcers	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Kidney Disease	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Bladder Disease	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Liver Cirrhosis	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Hepatitis A/ B/ C/ Other	Yes	No	I Don't Know	If yes, what type A B C Other _____ Date(s) of Diagnosis _____
Cancer	Yes	No	I Don't Know	If yes, What Type (s) _____ Date(s) of Diagnosis _____
Prostate Trouble (Men only)	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Abnormal Pap smear (Women only)	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Osteoporosis	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Multiple Sclerosis	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Stroke	Yes	No	I Don't Know	If yes, Date of Diagnosis _____

ID# \_\_\_\_\_

For Office Use Only

**SECTION 5: GENERAL MEDICAL HISTORY (continued)****Have you ever been told by a doctor that you had any of the following conditions?**

(Please circle the appropriate response and, if applicable, indicate the date of diagnosis.)

Parkinson's Disease	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Severe Head Injury — Loss of Consciousness or diagnosis of a Concussion by a physician	Yes	No	I Don't Know	If yes, specify type _____ Date of Diagnosis _____
Alzheimer's Disease or other Dementia	Yes	No	I Don't Know	If yes, specify type _____ Date of Diagnosis _____
Any Other Nervous System Condition	Yes	No	I Don't Know	If yes, specify type _____ Date of Diagnosis _____
HIV/AIDS	Yes	No	I Don't Know	If yes, specify type _____ Date of Diagnosis _____
Emotional Problems such as Clinical Depression or Anxiety Disorders	Yes	No	I Don't Know	If yes, Date of Diagnosis _____
Any Other Health Condition	Yes	No	I Don't Know	If yes, specify type _____ Date of Diagnosis _____
Have you lost weight in the last year?	Yes	No	I Don't Know	If yes, how many pounds? _____ For what reason _____

ID# \_\_\_\_\_

For Office Use Only

## **SECTION 6: MEDICATIONS**

The tables on the following pages are for you to list any medications (prescription or over-the-counter) or supplements that you have taken in the last **2 years**. Attached is a medications list that you can use as a guide to the major classifications of medications.

Please list all medications and supplements you have taken in the last **2 years**, including the name, dose, and how often you take (or took) the drug. For each item, please also indicate if it is something you are currently taking and how long you have been taking it. Please be as specific as possible about the exact drug taken and include all drugs you have taken, even if they are not on the attached medications list.

ID# \_\_\_\_\_ For Office Use Only \_\_\_\_\_

## SECTION 6: MEDICATIONS (continued)

Have you taken any *prescriptions, over-the-counter medications or supplements* in the last 2 years?      Yes      No

Medication Name	Dose	Times Taken	Do you use this medication now?	How long have you used this?	Use in the last 24 hours?
1)		_____ per: day week month year	Yes    No		F O R
2)		_____ per: day week month year	Yes    No		O F
3)		_____ per: day week month year	Yes    No		F I C E
4)		_____ per: day week month year	Yes    No		
5)		_____ per: day week month year	Yes    No		L S E
6)		_____ per: day week month year	Yes    No		O N L Y
7)		_____ per: day week month year	Yes    No		

# **MEDICATIONS LIST**

**This list serves only as a guide to major classifications of medications. Please be as specific as possible in the exact drug taken and include all drugs even if they are not on the list.**

Analgesics or Pain Killers

Insulin or other Diabetes Drugs

Antibiotics

Heart Medication

Stimulants

Hormones or Birth Control Medications

Thyroid Preparations

Diuretics

Tranquilizers

Anti-Depressants

Steroids

High Blood Pressure Medication

Vitamin and Mineral Supplements

Ulcer Drugs

Asthma or Allergy Medications

Homeopathic/Herbal Medicines

Sedatives or Sleeping Medications



ID# \_\_\_\_\_

For Office Use Only

## **SECTION 7: ACTIVITIES LOG**

---

The following section concerns your activity level during the **past 7 days**.

Please first indicate how much time you have spent (on average) sleeping each night, and if you have had any difficulty sleeping recently.

Then, please list the activities you have performed in the last 7 days, including how many total hours you spent doing each activity over the course of the week. Please list your activities according to whether they are mental or physical, and within the physical activities please categorize activities by how strenuous they are.

Attached is a list of examples of activities that you can use as a guide for this section. Please also include any activities you performed that are not listed on the attached list of examples.

---

---

**For Office Use Only**

---

---

During the last 7 nights, how many hours, on average, did you spend sleeping each night? \_\_\_\_\_ hours

Did you have any trouble sleeping last night or the night before? (Circle one)

Please list all of the activities you performed during the **past seven days** and indicate how many **total hours** (for the entire week ) you spent performing each activity. Please use the attached list of examples of activities as a guide for this section, but please also list activities you performed even if they are not on the list of examples. Please categorize your activities as physical or mental, and within the physical activities please categorize your activities as light, moderate, hard, or very hard based on how strenuous they are. We consider activities to be light if they are less strenuous than brisk walking. Activities are moderate if they produce feelings similar to brisk walking, and very hard if they produce feelings similar to running or jogging. Hard activities fall in between.

[illegible]

ID# \_\_\_\_\_

For Office Use Only

**SECTION 7: ACTIVITIES LOG (continued)**

	Specific Activity	Hours per Week
<b>Moderate Physical Activities</b> (similar to brisk walking)		
<b>Hard Physical Activities</b> (more than walking, less than jogging)		
<b>Very Hard Physical Activities</b> (similar to running or jogging)		

Compared to your physical activity over the past year, was last week's physical activity (circle one):    More    Less    About the Same

## SECTION 7: ACTIVITIES LOG (continued)

	Specific Activity	Hours per Week
Mental Activities (playing cards, board games, reading)		

Compared to your mental activity over the past year, was last week's mental activity (circle one):    More    Less    About the Same

# EXAMPLES OF ACTIVITIES

## **Mental Activity:**

Playing cards/board games, reading, crosswords, puzzles, data searches (by book or internet), writing, balancing budgets.

## **Light Physical Activity:** Less strenuous than brisk or fast walking

### **Occupational tasks**

Driving a car, light office work (sitting), typing

### **Household activities**

Folding clothes, making bed, watering lawn or garden, cooking, washing dishes

### **Leisure activities**

Knitting, sewing, walking (<2 mph)

## **Moderate Physical Activity:** Produces feelings similar to brisk or fast walking

### **Occupational tasks**

Machine tooling, assembling at a fast pace, delivering mail or patrolling on foot, house painting, carrying light (<25 lbs) objects

### **Household activities**

Food shopping (with cart), mowing the lawn with a power mower, general gardening, raking the lawn, sweeping and mopping, cleaning windows, carrying and stacking wood

### **Leisure activities (actual playing time)**

Brisk walking (3 mph), bicycle riding (<10 mph), golf (walking), volleyball, ping-pong, calisthenics exercises, slow dancing, moderate play with children, fishing from river bank, hunting small game

## **Hard Activity:** More strenuous than brisk or fast walking, but less strenuous than jogging

### **Occupational tasks**

Heavy carpentry, construction work, doing physical labor, carrying loads between 25 – 74 lbs

### **Household activities**

Scrubbing floors, moving furniture, chopping wood

### **Leisure activities (actual playing time)**

Tennis doubles, basketball, aerobic dancing, fast social/square dancing, active play with children, fishing in stream in waders, hunting large game

## **Very Hard Activity:** Produces feelings similar to running or jogging

### **Occupational tasks**

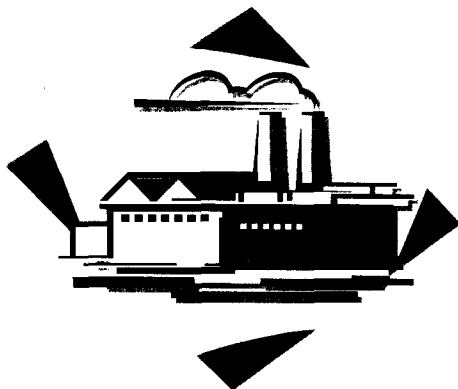
Very hard physical labor, such as digging or chopping with heavy tools, carrying heavy loads (75 lbs or greater) such as bricks or lumber

### **Household activities**

Carrying groceries or other household items (such as furniture or boxes) up stairs

### **Leisure activities (actual playing time)**

Jogging, swimming, tennis singles



# The Capacitor Workers Study

AMD17-02-1-0173

Annual Report—January 2004

DBs Alter Dopamine Mediated Function in Aging Workers

egal, Richard F., Principal Investigator

## APPENDIX 3

Recruitment Packet for  
New Haven, CT Based Testing



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center    The Governor Nelson A. Rockefeller Empire State Plaza    P.O. Box 509    Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr. P.H.  
*Commissioner*

Dennis P. Whalen  
*Executive Deputy Commissioner*

January 12, 2004

Name  
Address  
Address

Dear \_\_\_\_\_,

I would like to again thank you for participating in the first portion of the Capacitor Workers Study. Your results, when combined with those from other former workers, will allow us to determine if occupational exposure to PCBs is associated with neuropsychological and/or neurological changes. These data, however, cannot determine how PCBs alter brain function—understanding this may eventually lead to treatments that could minimize the potential deficits.

The second portion of the study involves imaging a special class of brain cells whose numbers decrease with aging, Parkinson's Disease, and in laboratory animals exposed to PCBs. This test, called Beta-CIT, can only be conducted in New Haven, CT at the Institute for Neurodegenerative Disorders. Although the enclosed material explains the procedures in more detail, I would like to provide a brief description of what participation would involve.

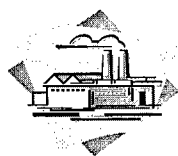
The brain imaging test requires a two-day stay in New Haven. On the first day you will receive a physical examination and an intravenous administration of a radio-labeled tracer. The amount of radiation in this injection is similar to that you would receive on an airplane flight between New York and California. On the second day, approximately 24 hours after receiving the tracer, you will undergo imaging that will take between 45 and 60 minutes. This test has been carried out in more than 1,000 individuals with no significant negative side effects.

We will, based on your preference, either provide 'door to door' car service between your home and the Institute (located across the street from the hotel) or reimburse you for the use of your own car at the rate of 36 cents per mile. Your hotel and food expenses at the hotel, as well as those of a companion, will be covered. You will also receive an additional honorarium of \$200.

I will call you in about a week to see if you have any questions and determine if you are interested in taking part in the second portion of the study. Again, I want to thank you for taking part in the Albany portion of the study and contributing to our understanding of how PCBs and related toxicants may affect brain function.

Best wishes,

Richard F. Seegal, Ph.D.  
Project Director



The Capacitor  
Workers Study



# IND

## Institute for Neurodegenerative Disorders

60 Temple Street  
Suite 8B  
New Haven, CT 06510

Phone: 203.401.4300  
Fax: 203.401.4301  
Web: [www.indd.org](http://www.indd.org)

Dear PCB- CIT Participant,

Thank you very much for your interest in PCB-CIT. Please read the enclosed consent describing this study. Do not sign this consent, you will sign it when you arrive at our offices in New Haven. You will find a "Most Frequently Asked Questions" sheet about  $\beta$ -CIT. We will contact you after we hear from your study coordinator to answer any questions you may have and give more detailed information about the study.

We have also included a brochure about the New Haven Hotel, where you will be staying, and information about New Haven. Upon arriving at the New Haven Hotel, you will receive a letter from us which will provide details of your schedule. Our staff will be available to answer any questions you may have.

In addition to the costs of air and ground transportation to and from New Haven, the study sponsor will pay for your hotel accommodations and meals at the hotel. A pool, health center, and cable television are available for your enjoyment complimentary of the hotel. Meals outside the hotel and costs for other services available at the hotel, including long distance telephone calls, faxing, and laundry, are not covered by the study. In keeping with the hotel's policy, you will be asked to present a credit card upon check in.

Should you require ground transportation to and/or from your home airport, please be sure to obtain a receipt for the expense. We will need the original receipts to reimburse you for the expense in the form of a check that you will receive by mail.

If you have any questions, please feel free to call Susan Mendick at 203-401-4337. We look forward to meeting with you and thank you for your interest in our study.

Sincerely,

Kenneth L. Marek, MD  
Principal Investigator  
Director of Research



## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE:** Dynamic SPECT Imaging with [<sup>3</sup>I]β-CIT in individuals at risk for parkinsonism due to an exposure to an environmental toxin potentially associated with parkinsonism.

**PROTOCOL NO.:** WIRB® 20021911

**SPONSOR:** Department of Defense  
Fort Detrick, MD 21702

**INVESTIGATOR:** Kenneth Marek, M.D.  
Institute for Neurodegenerative Disorders  
60 Temple Street, Suite 8B  
New Haven, CT 06510  
(203) 401-4300 (24-hour pager)

This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

### Invitation to Participate and Description of Study

You are invited to participate as a subject in a research study conducted at the Institute for Neurodegenerative Disorders. You are invited to participate in this study because you have been exposed to PCBs (polychlorinated biphenyls) which might cause Parkinson's disease or a related neurological problem.

Other neurological problems could include other shaking disorders, restless legs syndrome, walking disorders or thinking problems. Parkinsonism includes the symptoms of stiffness, slowness, decreased facial expression, softening of speech, tremors at rest and balance difficulties.

This study will investigate whether brain imaging with an investigational radioactively labeled drug, [<sup>3</sup>I]β-CIT, can provide useful pictures of the brain to increase our knowledge about potential genetic and environmental risk factors of parkinsonism. The investigational drug to be used in this study is not approved by the U.S. Food and Drug Administration (FDA) for commercial use. In this study you will be injected with [<sup>3</sup>I]β-CIT, and 24 hours later we will obtain pictures of the drug activity in your brain with SPECT imaging, which stands for single photon emission computed tomography (SPECT). Since this imaging information is investigational, it cannot provide specific information for you regarding your risk of developing parkinsonism. Therefore, we will not discuss your specific imaging results with you.

Approximately 96 research subjects will participate in this imaging study.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study which a member of the research study team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be done, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this consent form.

### **Description of Procedures**

If you agree to participate in this study you will have a screening examination by a neurologist to evaluate your neurological history and to conduct a thorough neurological exam. This will be done at the Institute for Neurodegenerative Disorders in New Haven, Connecticut. You will also have standard neuropsychological testing, including testing of memory, concentration, abstraction and visual spatial functions. Blood tests, urine tests and an electrocardiogram (ECG - tracing of the electrical activity of the heart) will also be obtained. These tests are to qualify you for the research study. The total screening procedure will take less than 3 hours to complete.

If you agree to participate and pass the screening requirement, you will have two outpatient visits for the [<sup>3</sup>I]β-CIT test. The [<sup>3</sup>I]β-CIT study will be done over two days, as described below:

**DAY 1** - You will report to Molecular NeuroImaging, LLC (MNI) where blood pressure measurements will be made and you will receive a standard dose of Lugol's solution (potassium iodide) by mouth (approximately 150 mg of iodine in 5 ounces of water) to reduce the amount of radioactive iodine that goes into your thyroid gland. We need to know if you have an allergy to iodine or shellfish so that we can give you potassium perchlorate tablets (1000 mg) instead of the Lugol's solution.

Next you will receive the intravenous (IV, into a vein) injection of the [<sup>3</sup>I]β-CIT, a radioactive material that concentrates in the brain. Women of childbearing potential will receive a urine pregnancy test before the injection. Blood pressure will be monitored at 15 minutes following the injection.

**DAY 2** - About 24 hours after the injection you will return to MNI for a SPECT scan. At this time, small markers will be placed on your skin which contain a minimal amount of radiation. You will then lie on a narrow table and your head will be placed in the SPECT camera. The remainder of your body remains outside the camera. The SPECT camera takes a "picture" of the radiation emitted by the [<sup>3</sup>I]β-CIT. You will lie motionless on the table for about 30 minutes while the camera takes pictures of your brain. You will be able to see out

of the camera and a study doctor will be with you during the test. You will be permitted to take a short break, if necessary, during the scanning session.

### **Risks and Inconveniences**

Risks from this study include radiation exposure from [ $^3\text{I}$ ]β-CIT, potential adverse (bad) effects of the [ $^3\text{I}$ ]β-CIT, radiation exposure from the markers attached to the skin, and having IV lines placed.

Radiation exposure from [ $^3\text{I}$ ]β-CIT: Guidelines have been established for the radiation dose considered acceptable for determination of radiotracer compounds in normal adult research subjects. The radiation exposure from this study is below the limits recommended. We will give a non-radioactive form of iodine (Lugol's solution) to minimize the radiation dose to the thyroid gland which uses iodine in the production of thyroid hormone.

Potential adverse effects of [ $^3\text{I}$ ]β-CIT: The study drug has been given to about 500 human subjects. Only minor side effects have been reported at these doses, like jaw and neck pain, heavy feeling in the head, bad taste in the mouth and swollen eyelids.

Administration of Lugol's solution before injection may cause a bad or unpleasant taste, over-active thyroid (Graves' disease), in at-risk subjects - allergic response with swollen eyelids and face, and rash. Administration of multiple doses of potassium perchlorate have caused fever, rash, swollen lymph glands, and kidney damage, but these problems have not occurred with a single dose of perchlorate.

In the event of unpleasant, potentially harmful effects of any drug given in this study, we will monitor your condition and start appropriate treatment.

There may be side effects which are unknown at this time.

Radiation exposure from the skin markers: The radiation exposure from the markers placed on the skin is well below the limits set, and can be considered low.

Risks of blood drawing: Inserting a narrow tube into a vein may cause discomfort. Sometimes a bruise will occur at the puncture site and on rare occasions, a blood clot or infection will occur in the vein. The total amount of blood withdrawn during the course of this study will be less than 1/2 ounce.

It may be difficult for you to lie still in the camera and may make several of the procedures difficult to tolerate. If you decide to withdraw from the study at any point, we will not question your decision and will appreciate your effort.

Women please note: If you are pregnant or breast-feeding you cannot take part in this research because radiation can cause severe damage to an unborn child. The procedure may

cause risks to the embryo or fetus which are currently unknown. Since the acceptable radiation levels for testing radiotracer compounds is lower in pregnant individuals, you cannot participate in this study if you are or might become pregnant during the period of the study. You will be tested for pregnancy. If the test is positive you will not be included in the study. Before your entering the study we will discuss with you in detail the need to avoid becoming pregnant and what precautions you plan to take. If you change your mind about becoming pregnant or regarding how you will avoid becoming pregnant, we will ask you to notify us immediately.

### **New Findings**

You will be told about any new information that might change your decision to be in this study.

### **Benefits**

There are no direct benefits to you. However, this test may improve our knowledge of potential risk factors of Parkinson's disease or related neurological problems.

### **Costs**

You will not be charged for any of the blood tests, scans, or travel expenses.

### **Payment for Participation**

You will be paid \$200.00 for participation in this study.

### **Alternatives**

This is not a treatment study. Your alternative is not to participate in this study.

### **Confidentiality**

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study.

It may also be given to the U.S. Food and Drug Administration (FDA). Research records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor; and
- representatives of the U.S. Army Medical Research and Materiel Command;

Feb 13, 2003  
AS MODIFIED  
WIRB®  
Olympia, WA

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA;
- Department of Health and Human Services (DHHS) agencies; and
- the Western Institutional Review Board® (WIRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. Study records will be kept confidential to the extent provided by law. Your name or other identifying information will not be used in any report or publication of this study.

Information will be maintained at the Institute for Neurodegenerative Disorders in a secure storage area for at least ten years after completion of the study. The Institute for Neurodegenerative Disorders study doctors will have access to the information as well as those already listed.

### **Compensation for Injury**

The United States Department of Defense is funding this research study. Should you be injured as a direct result of participating in this research study, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. This is not a waiver or release of your legal rights as a research subject. You should discuss this issue thoroughly with the study doctor before you enroll in this study.

### **Voluntary Participation/Withdrawal**

Your participation in this study is voluntary. You are free to choose not to participate. If you do become a subject you are free to withdraw from this study at any time during its course. If you choose not to participate or if you withdraw it will not adversely affect your relationship with your doctors or this hospital. Refusal to participate will involve no penalty or loss of benefits at this site.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

### **Questions**

If you have further questions about this research study, or if you feel you have experienced a research-related injury, contact the study doctor, Kenneth Marek, M.D., at (203) 401-4300 (24-hour pager).

Feb 13, 2003  
AS MODIFIED  
WIRB®  
Olympia, WA

If you have any questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)  
3535 Seventh Avenue, SW  
Olympia, WA 98502  
Telephone: 1-800-562-4789.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form.

**Consent**

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered.

I freely consent to participate in this research study.

I authorize the release of my medical records for research or regulatory purposes to the sponsor, the U.S. Army Medical Research and Materiel Command, the FDA, DHHS agencies, and WIRB®.

Subject Initials \_\_\_\_\_

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Permanent Address

\_\_\_\_\_  
Name of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Signature of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Principal Investigator (if different from above)

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Date

Subject Initials \_\_\_\_\_

-----Use the following only if applicable -----

*If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

\_\_\_\_\_  
Signature of Impartial Witness

\_\_\_\_\_  
Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

wirb/deptdefense/20021911/12-23-2002/srl/jlk  
mod. 02-13-2003/dsb/mpw

Subject Initials\_\_\_\_\_





## **$\beta$ -CIT-SPECT Brain Imaging Most Frequently Asked Questions**

---

### **1. What is the purpose of the study?**

Patients with Parkinson's disease have a loss of dopamine neurons in a area of the brain called the substantia nigra. The loss of these neurons may be one of the first pathological signs of Parkinson's disease. We are interested in determining whether this imaging study may provide information about the dopamine cells in people who have a family history or other risk factors for Parkinson's disease.

$\beta$ -CIT-SPECT imaging allows physicians to measure the number of dopamine neurons in the brain. This can be useful in evaluating whether there are signs of early changes in the dopamine neurons that may occur before the onset of symptoms. By repeating this imaging technique over time, we will be able to compare one scan to the next and learn if there are changes in the dopamine cells of people that may be at risk for Parkinson's disease. This imaging study may serve as a tool for the early diagnosis of Parkinson's disease and allow us to identify people that would be candidates for therapies that slow progression of the condition when they become available in the future.

### **2. What is $\beta$ -CIT?**

$\beta$ -CIT is a radioactively labeled drug that is injected into your vein and binds to the dopamine neurons in your brain. Using SPECT (Single Photon Emission Computed Tomography) imaging we are able to take pictures of that area of the brain containing the dopamine neurons.

### **3. Is the scan like having an MRI?**

No, only your head rests in the opening of the scanner. Your body is completely free and not confined. It is more like a CT scan.

### **4. How much radiation will I be exposed to?**

The FDA has established guidelines for the radiation exposure considered acceptable in normal adult volunteers. The exposure from this study is within limits specified by the FDA.

### **5. Are there any side effects?**

Although predictions of drug side effects in any individual cannot be made with certainty, to date we have noted no significant side effects in over 1000 people injected with  $\beta$ -CIT. You will be monitored throughout the study for any adverse effects.

## **$\beta$ -CIT-SPECT Brain Imaging Most Frequently Asked Questions**

### **6. Is there any discomfort associated with this procedure?**

Aside from the placement of an intravenous catheter for the purpose of injecting the drug, there is no discomfort associated with this procedure.

### **7. How long does the procedure take?**

The study is performed over two days. On Day 1, the injection will take place. The scan will be on Day 2. The isotope must be delivered from Vancouver on the morning of your injection in order to assure its viability. Your injection will take place in the early afternoon and takes about 15 minutes. The following day, the SPECT scan will take place over a 45 to 60 minute period. You may need to be seen by Dr. Marek or Dr. Jennings for a brief exam on either the injection day or the scan day.

### **8. Do I need to fast for this procedure? Should I take my usual medications prior to the injection or scan?**

You should eat as usual and take your normal medications.

### **9. Is there any cost to me associated with participating in this study?**

You will not be responsible for any costs of this test.

### **10. Will someone at the Institute for Neurodegenerative Disorders be available to answer other questions I might have?**

If you have any questions or concerns about this procedure, please contact Susan Mendick at (203) 401-4337.



Our research aims are to understand the changes that occur in Parkinson's disease as well as those that may be at risk for developing Parkinson's disease and to establish improved therapies for this disease. Thank you for your interest in participating in our study.

#### **APPENDIX 4**

Abstract from International Neurotoxicology Association (INA9)  
Meeting in Dresden, Germany, June 2003

## INTERNATIONAL NEUROTOXICOLOGY ASSOCIATION 2003

Does Occupational Exposure to Polychlorinated Biphenyls Alter Dopamine-Mediated Neurological Function? R.F. Seegal<sup>1</sup>, K. Marek<sup>2</sup>, S. Factor<sup>3</sup>, R. McCaffrey<sup>4</sup> and R. Haase<sup>4</sup>. <sup>1</sup>Wadsworth Center, New York State Dept. of Health, Albany, NY; <sup>2</sup>Institute for Neurodegenerative Disorders, New Haven, CT; <sup>3</sup>Albany Medical Center, Albany, NY and <sup>4</sup>University at Albany, Albany, NY.

Capacitor workers were exposed to PCBs resulting in serum levels 100-fold higher than in unexposed individuals. These levels may well be of concern since exposure of adult non-human primates to PCBs, resulting in serum PCB levels comparable to those seen in capacitor workers, reduced basal ganglia dopamine (DA) concentrations and the number of DA-containing neurons in the substantia nigra—even months after exposure ceased. Based on these data we conducted a pilot study of former capacitor workers (N=14) and age- and gender-matched controls (N=10) in which we measured neurological and neuropsychological performance and serum PCB levels. Because of the small N we used the partial  $r^2$  statistic to estimate significance in a larger study. Compared to controls, serum PCB levels and tremor, rigidity and bradykinesia were increased while reaction time and verbal memory performance were reduced. We are now undertaking a more comprehensive study of former capacitor workers. In addition to the above measures we are also determining basal ganglia DA transporter densities using  $\beta$ -CIT SPECT imaging and bone lead concentrations using X-Ray fluorescence. These studies will determine whether: (i) PCBs alter DA terminal densities (a marker of neuronal integrity); (ii) these reductions influence neurological and neuropsychological function and (iii) elevated lead exacerbates the predicted negative influences of PCBs on neurological outcomes. These studies will provide insights on the consequences and mechanisms of action of structurally and/or toxicologically similar contaminants (*e.g.*, dioxins and furans) on human DA function, including Parkinson's disease. Supported by the US Army Medical Research and Materiel Command.

## **APPENDIX 5**

Local Newspaper Article Written by an Albany Study Subject  
Describing Her Experience

# Taking the PCB test

As a past employee of the General Electric Co. at Fort Edward in the early 1950's, I was invited as a volunteer to participate in a research study on the health effects of occupational exposure to polychlorinated biphenyls (PCBs).

The staff of the state Department of Health, in cooperation with Albany Medical Center and the State University of New York at Albany are conducting the research study. The project is supported by a grant from the U.S. Army Medical Research and Material Command and involves multi-institution collaborations.

The goals of the research are to determine whether a relationship exists between serum PCB concentrations and/or duration of occupational exposure to PCB and adverse nervous system health effects and if any adverse effects become more apparent in aging workers.

Participants must be at least 50 and live within 100 miles of Albany. I volunteered to be a participant on Wednesday, June 18, a very interesting



**Helen  
Macura**

day. I learned a lot and I'm happy I volunteered.

My day began with Gwen Mergian, RN, study coordinator, picking me up at 6:30 and taking me to the Parkinson's Disease and Movement Disorders Center of Albany Medical Center, where I spent the morning.

Neuropsychological testing was administered by a qualified tester with SUNY-Albany. I found I was relaxed and comfortable throughout the test. You did not have to be a college graduate to answer questions or to participate in the tests.

The doctors and nurses were very professional and gracious at all times. So relaxed was I that I kept insisting on continuing on without requesting a break.

After my neurological examination I had to admit I was getting ready for

lunch and eager to lunch at the Crossgates Restaurant close by, within walking distance.

Upon arriving at the restaurant, we were seated in a comfortable small private dining area. We enjoyed lunch and the band playing in the next room.

I would like to compliment Gwen on picking the Crossgates Restaurant. I like fine dining. The waitress came over taking our order, giving us priority. She was warm and friendly and I certainly plan to return one fine day. Too bad we were in a hurry for our 1 p.m. appointment.

Shortly after 1 p.m. we arrived at the Empire State Plaza where I was further questioned about my background history and my work at the General Electric. I was tested to determine my bone level. Every test was given at a leisurely pace, never rushed.

I took home a cup saying "Thank You" on one side and on the other "The Capacitor Workers Study."

The tests given were confidential. If you are called to be a volunteer - go

for it. I certainly was glad I did, giving me ample time to discuss the PCB problems and similar health problems in Washington County.

I came home feeling I learned a lot; they had to admit there are a lot of people over the age of 50 who are very much alive and in good health who can contribute to society and their communities.

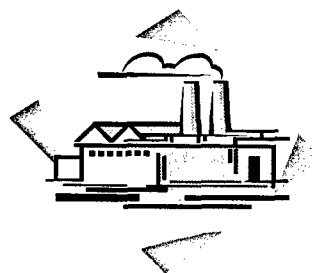
During one of the tests, I was required to write a sentence of my choice so that my hand writing could be tested. I wrote "I am having a great day - enjoying this experience, this chapter of my life."

Some of the participants may volunteer to participate at the institute for Neurodegenerative Disorders in New Haven, Conn., supported by the U.S. Army Medical Research and Material Command. I was offered this opportunity, but like others in the area, I declined, because it was not convenient for me.

I understand New Haven is the only place that has all the most sophisticated equipment doing these studies.

## **APPENDIX 6**

First Issue of a Study Update for Participants



---

## The Capacitor Workers Study

### Status Report - Summer 2003

---

#### **Rich's Corner**

First, let me thank you for the tremendous support you and your co-workers have shown during the first six months of the study. Indeed, without your cooperation and dedication, we could not carry out the project!

I plan on sending out an information bulletin approximately every six months. Over the next several years I would like to use this space to respond to suggestions and answer any questions you might have. Please feel free to contact me toll-free at 1-866-852-2561.

#### **Background on the project**

Dr. Rich Seegal recently received funds to carry out a study of the long-range neurological health risks associated with occupational exposure to polychlorinated biphenyls (PCBs). The project, funded by the United States Army Medical Research and Materiel Command, is a collaborative epidemiological study that involves staff from five institutions; The New York State Department of Health, Albany Medical Center, the University at Albany, Mt. Sinai School of Medicine, and the Institute for Neurodegenerative Studies in New Haven, CT.

Over the next three years we hope to evaluate 250 former capacitor workers who, like you, were employed by the General Electric capacitor factories in either Fort Edward or Hudson Falls. This study differs significantly from earlier ones because of our emphasis on the effects of PCBs on brain function and behavior.

#### **Why study PCBs?**

Based on studies of pregnant women who consumed PCB-contaminated fish, PCB exposure has been associated with lower scores on measures of memory and learning in their infants and children. Similarly, recent studies suggest that consumption of PCB-contaminated sport-caught fish by adults may also lead to poorer scores on tests of learning. Nevertheless, the effects of PCBs on the adult nervous system remain poorly understood.

One reason for this lack of understanding may be that studies of fish consumption have incorrectly assumed that PCBs are solely responsible for the observed changes. Fish from contaminated bodies of water contain a number of other chemicals that may contribute to the deficits in brain function. Still, while capacitor workers may have been exposed on the job to other substances that affect brain function, such as lead, the major exposure was to PCBs.

#### **Status update: the first six months**

We began enrolling participants in the Albany-based portion of the study in December 2002. Men and women who are medically eligible and live within 100 miles of Albany are invited to come to Albany for an interview, a blood test to measure current PCB levels, non-invasive testing of the nervous system, and an x-ray of the shin bone to determine past exposure to lead.

Despite challenges due to one of the worst winters on record, more than thirty men and women have participated in the project as of June. Since we schedule only one



appointment per day in Albany, which is typically on a Wednesday or Friday, it will take several years before the study is completed.

### **You guys are terrific!**

In a large-scale study of this kind, known as an epidemiological study, one of the most important factors in evaluating the overall success of the project is the rate of participation. So far, over 60 percent of workers asked to participate have agreed to do so. This response is exceptional-- quite a bit higher than the so called "gold standard" of 50% participation-- and speaks to the dedication of the men and women who have worked, and continue to work, at the capacitor factories.

### **How can this information be of use?**

Understanding the relationships between previous occupational exposure to PCBs and possible changes in nervous system function may ultimately lead to better treatment of workers who have been exposed to high levels of PCBs or other toxic chemicals that have similar effects on the nervous system.

### **The Connecticut study begins**

One mechanism by which PCBs may alter brain function is by decreasing concentrations of a brain chemical called dopamine. Indeed, studies of laboratory animals show that PCBs cause a reduction in the amount of dopamine in the brain.

In addition to the Albany-based study, we began the second part of the study in early April. Based in New Haven, Connecticut, this second part of the study provides additional information on possible changes in brain dopamine through the use of a brain imaging technology known as SPECT. This imaging allows physicians to actually measure the number of dopamine-containing

brain cells that a person has. As such, the Connecticut portion of the study will help us understand **how** PCBs alter brain function, by determining if exposure to PCBs on the job might reduce the number of brain cells that contain dopamine.

As with the Albany-based study, the rate of participation in the Connecticut-based study has been extraordinary. Approximately half of the workers asked to participate in this part of the study, which requires a two-day stay, have chosen to do so.

### **Why can't SPECT imaging be done closer to home?**

While other brain imaging techniques are widely available, SPECT is unique in its ability to gather information on dopamine-containing cells within a small portion of the brain. Unfortunately, at the present time, this technology is only available at the Institute of Neurodegenerative Studies in New Haven.

### **Thanks- from all of us**

Drs. Factor and Molho, Lyndsey, Brandon, Gwen, Susan, and I would once again like to thank you for taking the time to participate in the Albany and New Haven portions of the study. We look forward to meeting many more of your co-workers, and to the continued success of the project. We simply could not carry out this work without your support.

### **Want more information?**

If you have any questions, or would like more information on the project, please feel free to contact Dr. Rich Seegal at his toll-free phone number 1-866-852-2561.